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TO: Mr. Thomas L. Koontz **FROM:** Sherry Loke

COMPANY: U.S. Patent Office, OIPE **DATE:** September 12, 2005

FAX NO.: 1-703-308-7751 **NO. OF PAGES:**
(INCLUDING COVER SHEET) 11

SUBJECT/MESSAGE:

Re: U.S. Patent Application Docket No. TPI-T200XC1
HIGH-THROUGHPUT FORMATION, IDENTIFICATION AND ANALYSIS
OF DIVERSE SOLID-FORMS
(Cima, Levinson, Lemmo, Galakatos, Putnam)
Serial No. 09/756,092; filed January 8, 2001

Dear Mr. Koontz: Attached is a copy of a facsimile which I sent to Ms. Renee' Pattus (now Jones) on June 24, 2003 regarding the above-referenced patent application. As of this date, we have not yet received a corrected Filing Receipt. Please feel free to contact me if you have any questions or require any additional information to process this request. Thank you for your assistance in this matter.

The information contained in this facsimile message is intended only for the personal and confidential use of the designated recipients named above. This message may be an attorney-client communication, and as such is privileged and confidential. If the reader of this message is not the intended recipient or an agent responsible for delivering it to the intended recipient, you are hereby notified that you have received this document in error, and that any review, dissemination, distribution, or copying of this message is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return the original message by mail. Thank you.

If you do not receive all pages or if any transmission is not legible, call the sender at (352) 375-8100.

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TO: Ms. Renee' Pettus

FAX NO.: (703) 308-4407

FROM: Sherry Loke

DATE: June 24, 2003

NO. OF PAGES (INCLUDING COVER SHEET): 10

SUBJECT/MESSAGE:

Re: U.S. Patent Application Docket No. TPI-T200XC1
Serial No. 09/756,092; filed January 8, 2001

Dear Ms. Pettus: In accordance with my telephonic conference with Ms. Rosa Thomas concerning the above-referenced patent application, following is a copy of a Response to Request for Corrected Filing Receipt indicating that the continuity claimed under 35 USC 120 cannot be added. Also attached is a copy of a Preliminary Amendment dated July 26, 2002 which was filed by previous counsel in the subject application (I have not sent you Exhibit B of the Preliminary Amendment which is the detailed amendments to the claims). You will note on pages 1-2 of the Preliminary Amendment that Applicants requested that the paragraph on page 1, lines 4-7, of the specification be amended to indicate that Serial Numbers 09/628,667 and 09/540,462 are continuation-in-part applications. Please provide me with an updated Filing Receipt reflecting all the domestic priority claimed by the Applicants. Thank you for your assistance in this matter. If you have any questions or require additional information, please do not hesitate to contact me.

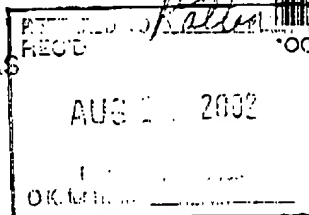
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UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, DC 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
09/756,092	01/08/2001	Michael J. Cima	10436-0009-999

20583
PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

CONFIRMATION NO. 5650

Date Mailed: 08/07/2002

RESPONSE TO REQUEST FOR CORRECTED FILING RECEIPT

Domestic Continuity and Foreign Priority

In response to your request for a corrected Filing Receipt, the Office is unable to comply with the request because:

- ☐ The priority or continuity claim has not been entered because it was not filed during the required time period. Applicant may wish to consider filing a petition to accept an unintentionally delayed claim for priority. See 37 CFR 1.55 or 1.78.
- ☒ Continuity claimed under 35 USC 120 cannot be added to the Filing Receipt without the applicant supplying the relationship (continuation, divisional, or continuation-in-part) in an Application Data Sheet or amendment to the first page of the specification.
SERIAL NUMBER 09/628,667 07/28/2000, 09/540,462 03/31/2000
- ☐ A claim for priority cannot be made based on an application filed after the application making the claim.
- ☐ Domestic and foreign priority claims will not be captured in a provisional application. A provisional application is not entitled to a right of priority or to the benefit of an earlier filing date of any other application. See 35 USC 111(b)(7) and 37 CFR 1.53(c)(4).
- ☐ A domestic continuity claim cannot be made to a foreign application and the filing receipt will only list the foreign country, application number, and filing date.
- ☐ Foreign priority will appear on the Filing Receipt in the following order:
Country, Application number, Filing date.

Nepu (Saregao)
Customer Service Center
Office of Initial Patent Examination
(703) 308-1202

EXPRESS MAIL NO.: EL 477 037 453 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Cirna et al.

Application No.: 09/756,092

Group Art Unit: 1627

Filed: January 8, 2001

Examiner: Baker, M.

For: HIGH-THROUGHPUT
FORMATION, IDENTIFICATION,
AND ANALYSIS OF DIVERSE
SOLID FORMS

Attorney Docket No.: 10436-009-999

**PRELIMINARY AMENDMENT AND RESPONSE TO RESTRICTION
REQUIREMENT UNDER 37 C.F.R. §§ 1.115 & 1.142**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed March 27, 2002, further to a teleconference with the Examiner and in accordance with the Rules of Practice, please enter the following amendments and consider the following remarks. Applicants submit concurrently with this preliminary amendment and response to restriction requirement: (a) Exhibits A-C which set forth detailed changes to the specification and claims and provide a clean copy of the pending claims following entry of this amendment; and (b) a petition for extension of time with provision for the required fee.

IN THE SPECIFICATION:

Please amend the specification as follows:

At page 1, lines 4-7 delete the paragraph:

--This application claims the benefit of U.S. Provisional Patent
Application Nos. 60/175,047 filed January 7, 2000; 60/196,821 filed April 13,

2000; and 60/221,539 filed July 28, 2000, all of which provisional applications are incorporated herein by reference in their entirety. --

and replace with the following paragraph:

"This application claims the benefit of U.S. Provisional Patent Application Nos. 60/175,047 filed January 7, 2000; 60/196,821 filed April 13, 2000; and 60/221,539 filed July 28, 2000, each of which is incorporated herein by reference in its entirety. This application is also a continuation-in-part of U.S. Patent Application No. 09/628,667 filed July 28, 2000, which is a continuation-in-part of Application No. 09/540,462, filed March 31, 2000; which claims priority to U.S. Provisional Patent Application No. 60/146,109, filed July 28, 1999 each of which is incorporated by reference in its entirety."

A marked up version of the above replacement paragraph, marked up to show all the changes relative to the previous version of the paragraph, is submitted herewith as Exhibit A. The changes are shown by underlining (for added matter).

IN THE CLAIMS:

Please amend claims 39, 43, 46, 49-50, and 52-53 as follows. A marked up version of pending claims is presented as Exhibit B and a clean copy of pending claims following entry of this preliminary amendment is presented in Exhibit C.

39. (Amended) A method of screening a plurality of solid-forms of a compound-of-interest, comprising:

- (a) preparing at least 24 samples each sample comprising the compound-of-interest and one or more components, wherein an amount of the compound-of-interest in each sample is less than 1 gram;
- (b) processing at least 24 of the samples to generate an array wherein at least two of the processed samples comprise a solid-form of the compound-of-interest; and
- (c) analyzing the processed samples to detect at least one solid-form.

43. (Amended) The method of claim 39, wherein one or more of the processed samples differ with respect to at least one of:

- (a) amount or concentration of the compound-of-interest;
- (b) the physical state of the solid-form of the compound-of-interest;
- (c) the identity of one or more of the components;
- (d) amount or concentration of one or more of the components;
- (e) a physical state of one or more of the components; or
- (f) pH.

46. (Amended) The method of claim 39, further comprising analyzing detected solid-form by infrared spectroscopy, near infrared spectroscopy, Raman spectroscopy, NMR, x-ray diffraction, neutron diffraction, powder x-ray diffraction, light microscopy, second harmonic generation, or electron microscopy.

49. (Amended) The method of claim 39, wherein one or more of the components is an excipient, a solvent, non-solvent, a salt forming component, a salt, an acid, a base, a gas, a pharmaceutical, a dietary supplement, an alternative medicine, a nutraceutical, a sensory compound, an agrochemical, an active component of a consumer formulation, an active component of an industrial formulation, a crystallization additive, an additive that affects particle or crystal size, an additive that structurally stabilizes crystalline or amorphous solid-forms, an additive that dissolves solid-forms, an additive that inhibits crystallization or precipitation, an optically-active solvent, an optically-active reagent, or an optically-active catalyst.

50. (Amended) The method of claim 39, wherein processing the samples comprises at least one of:

- (a) adjusting a value of temperature;
- (b) adjusting processing time;
- (c) adjusting pH;
- (d) adjusting amount or concentration of the compound-of-interest;
- (e) adjusting amount or concentration of one or more of the components;
- (f) adding one or more additional components;
- (g) nucleation;

- (h) precipitation; or
 - (i) controlling the evaporation of one or more of the components;
- or a combination thereof.

52. (Amended) The method of claim 51, wherein the form of the compound-of-interest is a salt, hydrate, anhydrous, co-crystal, dehydrated hydrate, solvate, desolvated solvate, clathrate, or inclusion.

53. (Amended) The method of claim 39, wherein the array comprises two or more polymorphs of the compound-of-interest.

REMARKS

First, Applicants thank the Examiner for the informative telephone interview on May 31, 2002.

Claims 39, 43, 46, 49-50, and 52-53 have been amended to particularly point out and distinctly claim the invention. The specification has also been amended to correct the continuing-application information for the present application. No new matter has been added by way of these amendments to the specification or the claims. Support for the amendments to the claims can be found throughout the specification, in particular, at page 26, line 28 - page 27, line 14. Applicants respectfully request that the present amendments be entered and the present remarks be made of record in the file history of the present application.

Originally filed claims 1-169 were made subject to the ten-way restriction requirement and an election of species as set forth on pages 2-24 of the Office Action of March 27, 2002. The restriction requirement requires an election under 35 U.S.C. § 121 of one of ten inventions identified as corresponding to claims in groups I to X respectively, as set forth in the Office Action. Applicants respectfully traverse the restriction requirement since examination of claims 1-169 does not require separate or burdensome searches as alleged in the Office Action. Moreover, efficient examination of the application will be impeded by the ten-fold restriction requirement that multiplies the prosecution costs at least ten-fold while imposing significant administrative costs on the Applicants.

However, in the event the restriction is maintained, Applicants hereby provisionally elect, with traverse, Group III containing claims 39-59, with claims 39-42, 58 and 59 being generic to the group, drawn to a method for testing or optimizing one or more properties of a formulation.

In accordance with the aforementioned election of Group III, and in response to the Examiner's request for a species election, as set forth at paragraph 17, page 11 of the Office Action, Applicants elect, with traverse, the following species, and Applicants respectfully request modification of the elections of subgroups E and F. As the Examiner will see, no additional burden or difficulty in searching is imposed by the requested modification of subgroups E and F.

- Subgroup A: Type of difference (claim 43), Applicants elect species 3, identity of one or more components;
- Subgroup B: Analysis Method (claims 44-45), Applicants elect image analysis;
- Subgroup C: Further Analysis Method (claims 46-47)¹, Applicants elect Raman spectroscopy;
- Subgroup D: identity of compound-of-interest (claim 48 & 55-57), Applicants elect species 1, pharmaceuticals, particularly small molecules;²
- Subgroup E: identity of component (claim 49)³, Applicants elect solvent and salt forming component;

¹ Applicants respectfully point out that this analysis of claim 46 is not necessarily in addition to other analysis, but instead can be the only analysis. Indeed, the dependencies of claim 45 and 46 are distinct.

² Applicants respectfully traverse the Examiner's requirement that a specific compound be elected as unduly limiting and inappropriate given the claim language, focus of the method and disclosure of the application. Nevertheless, to be responsive, Applicants elect with traverse ritonavir.

³ Applicants respectfully point out that the recited election will actually aid in the search in view of the customary, but not required, practice of adjusting solvent and salt forming component simultaneously. In the event the Examiner does not agree to the modification, Applicants provisionally elect solvent with traverse. Applicants respectfully traverse the Examiner's requirement that a specific compound be elected as unduly limiting and inappropriate given the claim language, focus of the method and disclosure of the application. Nevertheless, to be responsive, Applicants elect with traverse ethanol.

- Subgroup F: type of processing parameter (claim 50), Applicants elect adjusting temperature and or the amount or concentration of the compound-of-interest or components⁴; and
 - Subgroup G: type of Solid form (claims 51-54), Applicants elect crystalline.
- Applicants respectfully submit that all of the elected claims read on the elected species.

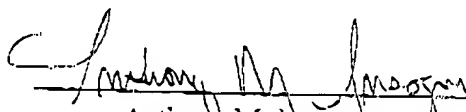
CONCLUSION

Applicants have traversed the restriction requirement and species elections and hereby request that either the restriction requirement and species election be withdrawn in view of the reasons recited herein or be made final. In the alternative, modification of the species election and acceptance of the provisional elections are respectfully requested. An early allowance of the application is earnestly requested. The Examiner is invited to contact the undersigned with any questions concerning the foregoing.

It is estimated that no fee in addition to that required for the extension of time is necessary for filing this response. In the event a fee is required, please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date July 26, 2002

 35,203
Anthony M. Insogna (Reg. No.)

PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, New York 10036-2711
(212) 790-9090

⁴ Typically, but not as a requirement, both temperature and the amount or concentration of compound-of-interest or components are varied to effect crystallization. Thus, the election of all three is intended to assist the Examiner in the search in view of the discussion during the telephone conference. The election is consistent with the recitation of "combinations" in claim 50, but is made to avoid limiting the permissible scope of combinations. However, in the event the Examiner does not agree to the modification, then temperature may be used to direct an initial search followed by amount or concentration of compound-of-interest or components to further refine the search.